IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

CAREMARK, LLC, and CAREMARKPCS HEALTH, LLC, Plaintiffs, v. GENTNER DRUMMOND, in his official capacity as Attorney General of Oklahoma, Defendant.	Civil Action No. CIV-24-62-HE

COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF

Plaintiffs Caremark, LLC and CaremarkPCS Health, LLC (together, "Caremark") allege as follows:

INTRODUCTION

1. Health plans structure prescription drug benefits in various ways to facilitate access to care, promote high-quality service, and minimize costs for the plan and members alike. When health plans are subject to the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq.*, or the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Part D" or "Part D"), those federal laws expressly preempt regulation of plan benefit structures by the states. ERISA and Medicare Part D plans must comply with the requirements of federal law—and because such plans are governed by federal law, states may not impose their own restrictions on the plans' benefit designs.

2. Oklahoma's Patient's Right to Pharmacy Choice Act (the "Act"), 36 O.S. § 6958 *et seq.*, endeavors to regulate ERISA and Medicare Part D plan benefit designs and is preempted by federal law to the extent it does so, as the Tenth Circuit recently held. In *Pharmaceutical*

Care Management Association v. Mulready, 78 F.4th 1183 (10th Cir. 2023), the Tenth Circuit considered multiple provisions of the Act and concluded that *each and every one* was expressly preempted. This action seeks a declaration under 28 U.S.C. § 2201 that ERISA and Medicare Part D likewise preempt certain other provisions of the Act that were not before the Tenth Circuit.

3. Given complexities unique to pharmacy benefits, most plans rely on specialized third-party service providers known as pharmacy benefit managers ("PBMs") to administer the plans' pharmacy benefits. The Act effectively regulates the pharmacy benefits that health plans may *offer* by regulating what benefits PBMs may *administer*. As the Tenth Circuit recognized, following longstanding Supreme Court precedent, the Act has "substantial, indirect effects" on plans themselves and is therefore preempted despite purporting to regulate only PBMs. *Mulready*, 78 F.4th at 1200.

4. As relevant here, the Tenth Circuit held in *Mulready* that ERISA preempts provisions of the Act that would have required PBMs to include in their retail pharmacy networks brick-and-mortar pharmacies satisfying certain geographic requirements; that would have prohibited PBMs from offering reduced copayments and other cost-sharing discounts to encourage beneficiaries to fill prescriptions at particular in-network mail-order pharmacies rather than retail pharmacies; and that would have required PBMs to include in their preferred pharmacy networks any pharmacy willing to accept the applicable preferred-network terms. The court reasoned that these provisions impeded PBMs' ability to offer "customized pharmacy networks" and effectively forced them to offer "a single-tiered network with uniform copayments, unrestricted specialty-drug access, and complete patient freedom to choose a brick-

and-mortar pharmacy." *Id.* at 1199. In short, they "mandate[d] benefit structures" of the State's choosing, which "ERISA forbids." *Id.*

5. The *Mulready* court also held that Medicare Part D preempted the provision requiring plans to include in their preferred networks any pharmacy willing to accept the applicable terms, because that provision "establishe[d] a rule that governs PBM pharmacy networks for Part D plans" and thus regulated "with respect to" Part D plans, contrary to the Part D statute. *Id.* at 1208.

6. In this action, Caremark challenges different provisions of the Act that are preempted for the same reasons.

7. Specifically, ERISA preempts 36 O.S. § 6961(C) (the "Affiliated Pharmacy Prohibition"), which forbids PBMs from requiring plan members to fill any prescriptions at pharmacies affiliated with the PBM; 36 O.S. § 6961(D) (the "Provider Identification Provision"), which prohibits PBMs from naming any pharmacy or other provider in mail, ID cards, or any other material unless the PBM also lists *all* pharmacies or other providers in the PBM's preferred and nonpreferred networks; and 36 O.S. § 6963(D) (the "Network Provider Restriction Prohibition"), which provides that plans and PBMs "shall not restrict an individual's choice of in-network provider for prescription drugs." These provisions, like the provisions the Tenth Circuit held preempted in *Mulready*, frustrate plans' ability to customize the pharmacy benefits they offer to their members and effectively mandate particular benefit structures, contrary to ERISA.

8. Medicare Part D also preempts the Affiliated Pharmacy Prohibition and Network Provider Restriction Prohibition because these laws purport to govern the pharmacy benefits that Part D plans may offer and thus act "with respect to" Part D plans, triggering preemption.

9. Oklahomans benefit from employers and other health plan sponsors having discretion to tailor the benefits they offer plan members. The Affiliated Pharmacy Prohibition, Provider Identification Provision, and Network Provider Restriction Prohibition forbid plans to offer benefit structures that are good for Oklahomans, including benefit structures that allow plan sponsors to limit the expenses borne by plan members and to offer a broader array of benefits, as well as benefit structures that promote patient adherence to medication and thus overall patient health. Today, the Act is preventing plan sponsors from offering the benefits they want, and even benefits they have promised under collective bargaining agreements.

10. Recognizing that it is good for *all* Americans when health plans are able to choose what benefit structures to offer, in ERISA and Medicare Part D Congress codified its judgment that that choice belongs to plans, not states. In those statutes' preemption provisions, Congress also recognized the importance of nationally uniform plan administration, which plans cannot maintain when states enact disparate regulations.

11. This Court should declare that these provisions of the Act, like the provisions the Tenth Circuit considered in *Mulready*, are preempted by federal law, and the Court should enjoin defendants from enforcing them.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 because this action arises under federal law.

13. This Court has personal jurisdiction over defendants, whose principal place of business is in the Western District of Oklahoma.

14. Venue is proper in this district under 28 U.S.C. § 1391 because the events giving rise to Caremark's claims occurred in this district and defendants reside in the State of Oklahoma.

THE PARTIES

15. Plaintiff Caremark, LLC, licensed as a PBM in Oklahoma, is a California limited liability company, headquartered at 9501 E. Shea Blvd., MC024, Scottsdale, Arizona 85260.

16. Plaintiff CaremarkPCS Health, LLC, licensed as a PBM in Oklahoma, is a Delaware limited liability company with its headquarters at 9501 E. Shea Blvd., MC024, Scottsdale, Arizona 85260.

17. Defendant Gentner Drummond is the Attorney General of the State of Oklahoma (the "Attorney General"). The Attorney General's principal place of business is in Oklahoma City, Oklahoma. The Attorney General is sued solely in his official capacity.

18. The Attorney General formally assumed responsibility for enforcing the Act on November 1, 2023. Glen Mulready, the Insurance Commissioner for the State of Oklahoma (the "Commissioner"), and the Oklahoma Insurance Department (the "Department"), were previously responsible for enforcing the Act.

FEDERAL PREEMPTION

19. The Supremacy Clause "exalts the U.S. Constitution and federal law as 'the supreme Law of the Land'" and "imbues Congress with 'the power to preempt state law.'" *Mulready*, 78 F.4th at 1192 (first quoting U.S. Const. art. VI, cl. 2; and then quoting *Arizona v. United States*, 567 U.S. 387, 399 (2012)). "Congress can exercise this power expressly, by defining a statute's preemptive reach in a preemption clause, or impliedly, by legislating in such a way to crowd out related state laws." *Id.* at 1193.

20. This case concerns preemption under two statutes, ERISA and Medicare Part D, which "both contain express preemption clauses." *Id.* Courts assessing preemption under these clauses "look to congressional intent as [the] 'ultimate touchstone.'" *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). And "the best evidence of Congress' preemptive intent"

is found in "the plain wording of the clause[s]" themselves. *Id.* (quoting *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 594 (2011)).

21. Congress passed ERISA "to make the benefits promised by an employer" to its employees "more secure by mandating certain oversight systems and other standard procedures," which Congress "intended to be uniform." *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 320-21 (2016). "To this end, ERISA includes expansive pre-emption provisions, which are intended to ensure that employee benefit plan regulation would be exclusively a federal concern." *Aetna Health Inc. v. Davila*, 542 U.S. 200, 208 (2004) (citation and quotations omitted). This statutory scheme ensures that "employers have large leeway to design [employee benefit] plans as they see fit." *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 833 (2003). Congress thus expressly provided that ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" within the statute's scope. 29 U.S.C. § 1144(a).

22. ERISA's "saving clause" provides that nothing in ERISA "shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities." *Id.* § 1144(b)(2)(A). But Congress qualified the "saving clause" with a "deemer clause" that "closes the saving clause's loophole" for certain employer-sponsored plans. *Mulready*, 78 F.4th at 1204. The "deemer clause" provides that no "employee benefit plan … shall be deemed to be an insurance company or other insurer … for purposes of any law of any State purporting to regulate insurance companies [or] insurance contracts." 29 U.S.C. § 1144(b)(2)(B). Together, the clauses allow states to continue to regulate insurance companies and thus the benefits offered in "fully insured" benefit plans, in which an employer purchases an insurance policy to cover employees, but forbid states to regulate "self-funded" (or "self-insured" or "uninsured") benefit plans, in which the employer pays for covered employees'

medical claims out of its own assets. *FMC Corp. v. Holliday*, 498 U.S. 52, 64 (1990) ("[I]f a plan is [fully] insured, a State may regulate it indirectly through regulation of its insurer and its insurer's insurance contracts; if the plan is uninsured"—i.e., self-funded—"the State may not regulate it."); *see also Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 747 (1985).

23. In 2003, Congress created Medicare Part D. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Medicare Part D is a public-private partnership between the Centers for Medicare & Medicaid Services ("CMS") and private insurers ("plan sponsors"). Beneficiaries receive their benefits through plan sponsors, which rely on PBMs to negotiate with pharmacies for competitive pricing and service arrangements. *See* 42 U.S.C. § 1395w-102(d). Plan sponsors compete to attract Medicare recipients to their prescription drug plans by offering different coverage options and lower out-of-pocket expenses. Plan sponsors must abide by the Medicare Part D statute itself, and CMS has promulgated additional standards that comprehensively regulate the operations of both Medicare Part D plans and, by extension, the PBMs that serve them. *See* 42 C.F.R. § 423.505(i) (specifying requirements for contracts between Medicare Part D plan sponsors and first-tier entities, such as PBMs).

24. To prevent states from interfering with the administration of the Medicare Part D benefit, Congress included in the Medicare Part D statute a broad express preemption provision imported from Medicare Part C. *See* 42 U.S.C. § 1395w-112(g). That preemption provision reads: "The standards established under [Part D] shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [prescription drug] plans which are offered by [plan sponsors] under [Part D]." *Id.* § 1395w-26(b)(3).

FACTUAL BACKGROUND

A. The Prescription Drug Market

25. Prescription drugs are a core component of modern healthcare in the United States. Two-thirds of American adults—more than 131 million people—use prescription drugs. Georgetown Univ. Health Pol'y Inst., *Prescription Drugs*, https://bit.ly/3SWwYjH (last visited Jan. 14, 2024). Prescription drugs are particularly important treatments for chronic conditions. 98% of people with diabetes and 89% of people with arthritis take prescription drugs, as do the vast majority of people with heart disease, hypertension, and cancer. *Id.*

26. There are five key players in the prescription drug market: manufacturers, wholesalers, pharmacies, health plans, and PBMs. *Mulready*, 78 F.4th at 1188-90. Manufacturers make drugs and drug ingredients, which they sell to wholesalers, who sell to pharmacies. *Id.* at 1188. Individuals fill prescriptions at brick-and-mortar (also called "retail") pharmacies or through the mail. *Id.* Some pharmacies are part of chains, while others are independent. *Id.* Most individuals access their prescription drugs through health plans, which can be employer-sponsored plans, Medicare Part D plans, or individual plans. *Id.* Each health plan decides what prescriptions it will cover, what it and its beneficiaries will pay for those prescriptions, and where beneficiaries fill their prescriptions. *Id.* These terms make up the plan's "benefit design or structure." *Id.*

27. In Oklahoma, approximately 3.4 million residents are covered by public or private insurance, of whom 1.68 million are covered by employer-sponsored health plans. KFF, *Health Ins. Coverage of the Total Population*, https://bit.ly/3PzlVgg (last visited Jan. 14, 2024). More than 500,000 Oklahomans have Medicare Part D prescription drug benefits. KFF, *Medicare Beneficiaries Enrolled in Part D Coverage*, https://bit.ly/3RBVitK (last visited Jan. 14, 2024).

28. To furnish prescription drug benefits, most health plans contract with PBMs, which provide the infrastructure, resources, and expertise necessary to navigate the enormous complexities and administrative difficulties of providing these benefits. *Mulready*, 78 F.4th at 1188-89. PBMs typically manage interactions between health plans and pharmacies, including processing and payment of claims and implementing clinical programs like patient adherence and medication management. *Id.* PBMs are indispensable to most health plans in administering prescription benefits, and "the vast majority of insured Americans receive their pharmaceutical benefits through a PBM." *PCMA v. District of Columbia*, 613 F.3d 179, 183 (D.C. Cir. 2010); *see Mulready*, 78 F.4th at 1188-89 (finding PBMs administer prescription drug benefits for 2.4 million Oklahomans and 270 million people across the country).

29. Health plan sponsors have authority to design the prescription drug benefits that their plans offer even when they contract with PBMs to administer these benefits. *See Mulready*, 78 F.4th at 1189. Plans can choose a PBM based on the network options they wish to offer, or they can direct a PBM to create a customized network. *See id.* PBMs offer health plans the tools and mechanisms to administer the prescription drug benefits that the plans choose to offer, but the plans themselves are the final decisionmakers about a prescription drug benefit's design and structure. *See id.*

30. To meet plans' goals, PBMs create and manage pharmacy networks, which are selected groups of contracted pharmacies where plan beneficiaries may access covered prescription drugs at prices and on terms and conditions agreed to between the PBM and network pharmacies. *Id.* Networks may include independent retail pharmacies, chain retail pharmacies, mail-order pharmacies, and specialty pharmacies, among others. *Id.*

31. Pharmacy network structure is a core component of plan prescription benefit design itself. *See id.* at 1198, 1201. Health plans often use pharmacy networks to promote health by encouraging beneficiaries to use pharmacies deemed likely to help beneficiaries adhere to prescribed treatments and to maximize plan resources and minimize costs—which can facilitate efficiencies that allow the plan to offer lower premiums or a broader array of benefits. ERISA plans also design pharmacy networks to fit the size and demographics of their employee populations.

32. When a beneficiary fills a prescription at a pharmacy, the pharmacy verifies, through the PBM, the beneficiary's plan benefits and copay arrangement. *See id.* at 1189.

33. To improve access, quality of care, and plan and beneficiary cost-efficiency, health plans may employ one or more common pharmacy network mechanisms and designs, including preferred pharmacy networks and requirements to fill certain prescriptions at certain pharmacies. *Id.* at 1189.

34. Many PBMs create preferred pharmacy networks, which allow plans and beneficiaries to pay less for prescriptions than at pharmacies in standard networks. *Id.* Preferred pharmacy networks benefit plan members through lower copays and other cost-sharing discounts. *Id.* Plans benefit because pharmacies agree to lower reimbursement rates in exchange for participation in the preferred pharmacy network. *Id.* Pharmacies agree to participate in preferred pharmacy networks and accept lower reimbursement rates to attract more business, because lower copays and other discounts attract more members to preferred pharmacies. *Id.*

35. Many plan benefit structures require or encourage members to make use of mail-order pharmacies. Some plans elect to cover prescriptions at mail-order pharmacies on the same terms as brick-and-mortar pharmacies, while others elect to design their benefits to require the

use of mail-order pharmacies for certain prescriptions. Mail-order pharmacies generally have greater purchasing power and lower acquisition costs than independent retail pharmacies and often accept lower reimbursement amounts as a result, and plans design their benefits to share these cost savings with beneficiaries. *See id.* Plans also adopt structures that encourage the use of mail-order pharmacies because they improve patient adherence to medication, which in turn enhances clinical outcomes—beneficiaries can obtain their prescriptions without physically traveling to the pharmacy and following the pharmacy's retail schedule. *See id.*

36. Plans may also elect to require or motivate beneficiaries to fill some prescriptions through pharmacies affiliated with the PBM, which are often but not always mail-order or specialty pharmacies, which can allow the PBM to offer more seamless service to health plans and their members. Through these benefit structures, PBMs can secure better rates for plans and help them offer enhanced disease management and care coordination programs to their members through their medical and pharmacy benefits.

37. When designing and structuring pharmacy networks, plans consider factors including access, quality of care, and cost to the plan and beneficiaries. Employers have the best insight to determine the best ways for their employees to access covered prescription drugs and full authority to tailor their pharmacy networks accordingly. Health plans also have discretionary power to design pharmacy networks to reduce costs to the plan and its beneficiaries, seeking to maximize the value of healthcare items and services—for instance, by providing generic medications or less expensive brands and requiring the use of certain pharmacies—and in turn allowing the plan to offer more generous benefits with lower beneficiary premiums and cost-sharing.

B. The Patient's Right to Pharmacy Choice Act

38. Governor Kevin Stitt signed the Patient's Right to Pharmacy Choice Act into law on May 21, 2019, and the Act took effect on November 1, 2019.

i. Act Background

39. The Act broadly establishes "minimum and uniform access to a provider and standards and prohibitions on restrictions of a patient's right to choose a pharmacy provider." 36 O.S. § 6959. It does this by "target[ing] PBMs and their pharmacy networks," which "bolsters the bargaining power of independent Oklahoma pharmacies." *Mulready*, 78 F.4th at 1190.

40. More specifically, the Act purports to impose a wide range of restrictions on PBMs. These include, among other things, geographic requirements for PBMs in designing their pharmacy networks, mandating the percent of covered Oklahomans in urban, suburban, and rural areas who must live within certain distances of a network or preferred retail pharmacy (and specifying that mail-order pharmacies cannot be used to meet these standards) (the "Access Standards," 36 O.S. § 6961(A)-(B)); mandates that PBMs may not deny any pharmacy the ability to participate in the network as "preferred" if the pharmacy accepts the terms and conditions that the PBM sets for preferred pharmacies (the "Any Willing Provider ('AWP') Provision," *id.* § 6962(B)(4)); and prohibitions on PBMs restricting an individual's choice of retail or mail-order pharmacy, such as by requiring or incentivizing the use of any discounts in cost-sharing or copays (the "Discount Prohibition," *id.* § 6963(E)).

41. The Act also creates restrictions on claims-adjudication processes and termination of pharmacies from networks, *see id.* §§ 6962(B)(2)-(3), (B)(5)-(7), (C)(3); requires health insurers to monitor all activities carried out on the insurer's behalf under the Act, *see id.* §§ 6963-6964; and provides investigatory and enforcement provisions, *see id.* §§ 6965-6967.

ii. Provisions Challenged In This Complaint

42. Caremark challenges three of the Act's network restrictions. First, the Act's "Affiliated Pharmacy Prohibition" provides that PBMs "shall not require patients to use pharmacies that are directly or indirectly owned by the [PBM], including all regular prescriptions, refills or specialty drugs regardless of day supply." *Id.* § 6961(C).

43. Second, the Act's "Provider Identification Provision" provides that PBMs "shall not in any manner on any material, including but not limited to mail and ID cards, include the name of any pharmacy, hospital or other providers unless it specifically lists all pharmacies, hospitals and providers participating in the preferred and nonpreferred pharmacy and health networks." *Id.* § 6961(D).

44. Finally, the Act's "Network Provider Restriction Prohibition" instructs: "A health insurer or [PBM] shall not restrict an individual's choice of in-network provider for prescription drugs." *Id.* § 6963(D).

45. These provisions—both individually and cumulatively—sharply restrict PBMs' ability to customize pharmacy networks to the needs of plan sponsors and plan members. They do so by requiring PBMs and plans to structure benefits in certain ways, particularly with regard to which pharmacies are included in a pharmacy network, where beneficiaries may obtain their prescriptions, and what the PBM or plan may say about their network. These provisions thereby make it harder for PBMs to attract pharmacies to participate in preferred pharmacy networks with the promise of increased volume and to tailor their pharmacy networks; meanwhile, plan members miss out on lower copays, cost-sharing discounts for using preferred pharmacies, and other benefits of a specially designed network.

C. The *Mulready* Litigation

46. Before the Act took effect, the Pharmaceutical Care Management Association ("PCMA"), a national trade association that represents PBMs, filed a federal complaint in this District, arguing that ERISA and Medicare Part D preempted many of the Act's provisions. PCMA and the State defendants eventually filed cross-motions for summary judgment on the preemption issues.

47. The district court issued a decision largely siding with the State. As relevant here, the district court ruled that ERISA did not preempt any of the challenged provisions and that Medicare Part D preempted the Access Standards (based on the court's own analysis), as well as the Provider Identification Provision and Discount Prohibition (based on the State's concession); the court also ruled that Medicare Part D did not preempt the Act's AWP Provision, Affiliated Pharmacy Prohibition, or Network Provider Restriction Prohibition. *See PCMA v. Mulready*, 598 F. Supp. 3d 1200, 1213 (W.D. Okla. 2022), *rev'd*, 78 F.4th 1183.

48. PCMA appealed. PCMA argued that the district court erred in rejecting its ERISA preemption challenge to the Access Standards, Discount Prohibition, and AWP Provision, and its Medicare Part D preemption challenge to the AWP Provision. PCMA did not appeal the district court's rulings under ERISA or Medicare Part D on the Affiliated Pharmacy Prohibition and Network Provider Restriction Prohibition, nor did PCMA appeal its ERISA preemption challenge to the Provider Identification Provision.

49. The Tenth Circuit reversed, agreeing with PCMA that federal law preempts every provision it challenged on appeal. *Mulready*, 78 F.4th at 1187.

50. First considering the ERISA challenge, the Tenth Circuit began its analysis by explaining that ERISA preempts "two categories of state laws that have [an] impermissible connection with ERISA plans: 'laws that require providers to structure benefit plans in particular

ways, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status,' and laws whose 'acute, albeit indirect, economic effects … force an ERISA plan to adopt a certain scheme of substantive coverage.'" *Id.* at 1194 (footnote omitted) (quoting *Rutledge v. PCMA*, 592 U.S. 80, 86-87 (2020)). The court observed that state laws impermissibly regulate plan benefit structures not only when they "mandate[] [certain] employee benefit structures," but also when they "prohibit[] employers from structuring their employee benefit plans in a certain manner"—i.e., that ERISA prohibits states from either demanding *or forbidding* particular benefit structures. *Id.* at 1194 n.6 (first quoting *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 658 (1995); and then quoting *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983)).

51. The Tenth Circuit readily found that the challenged provisions of the Act "succumb to ERISA preemption" because they "mandate benefit structures; they at least 'eliminate[] the choice of one method of structuring benefits,'" contrary to federal law. *Id.* at 1198 (quoting *CIGNA Healthplan of La., Inc. v. Louisiana ex rel. Ieyoub*, 82 F.3d 642, 648 (5th Cir. 1996)). "The Access Standards dictate which pharmacies must be included in a PBM's network, and on top of that, the AWP Provision requires that those pharmacies be invited to join the PBM's preferred network." *Id.* "The Discount Prohibition," for its part, "requires that cost-sharing and copayments be the same for all network pharmacies," forbidding distinctions between retail and mail-order pharmacies. *Id.* Each of the three challenged provisions thus "either directs or forbids an element of plan structure or benefit design." *Id.*; *see also id.* at 1199 ("Each network restriction winnows the PBM-network-design options for ERISA plans, thereby hindering those plans from structuring their benefits as they choose."). The court accordingly

held that ERISA preempts the Access Standards, the AWP Provision, and the Discount Prohibition. *Id.* at 1201.

52. The Tenth Circuit then turned to Medicare Part D, beginning by analyzing "the scope of Part D's preemption clause." *Id.* at 1205. The court observed that "Congress used unmistakably broad language" in that clause, *id.*, which provides that "[t]he standards established under [Part D] shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [prescription drug plans] which are offered by [plan sponsors] under [Part D]," 42 U.S.C. § 1395w-26(b)(3). "'Any' is expansive," and "[e]qually broad is the phrase 'with respect to'"; as a result, "[r]eading the clause naturally, Part D's standards preempt all state laws concerning Part D plans." *Mulready*, 78 F.4th at 1205-06. The Tenth Circuit thus rejected Oklahoma's argument that "the preemption clause's text requires a federal-state overlap"; instead, the court "agree[d] with PCMA that the sweeping Part D preemption clause is 'akin to field preemption' and precludes States from regulating Part D plans except for licensing and plan solvency." *Id.* at 1206.

53. Applying this interpretation of the preemption clause, the court found that Medicare Part D plainly preempts the AWP Provision: "The AWP Provision regulates 'with respect to [Part D plans]' because it establishes a rule that governs PBM pharmacy networks for Part D plans. And because it is not a licensing law or a law relating to plan solvency, the AWP Provision is preempted." *Id.* at 1208 (alteration in original) (citation omitted) (quoting 42 U.S.C. § 1395w-26(b)(3)).

54. Summing up its decision, the court of appeals emphasized that the judicial "role is to answer whether the Act's … challenged provisions veer into the regulatory lanes that Congress has reserved for itself." *Id.* at 1209. The court concluded that was the case for all the

provisions before it: "Though the Act avoids mentioning ERISA plans or Medicare Part D plans by name, it encompasses these plans by striking at the heart of network and benefit design." *Id.* That did not leave states without any "avenue by which to meaningfully seek redress," but that avenue was to "approach Congress, the architect of ERISA and Medicare, to take up the mantle"—not to enact state legislation in an area Congress expressly designated the exclusive province of federal law. *Id.*

55. The Tenth Circuit therefore reversed and remanded, holding "that ERISA preempts the Access Standards, Discount Prohibition, [and] AWP Provision … as applied to ERISA plans," and "that Medicare Part D preempts the AWP Provision as applied to Part D plans." *Id.*

56. On September 13, 2023, defendants filed a petition for rehearing en banc. On September 24, the panel ordered PCMA to respond to the petition, which it did on October 16. The Tenth Circuit denied the petition on December 12, 2023, and denied a motion to stay the mandate on January 2, 2024. The mandate in the case issued on January 10, 2024.

D. *Mulready* Extends To The Provisions Caremark Challenges In This Action

57. The Affiliated Pharmacy Prohibition, Network Provider Restriction Prohibition, and Provider Identification Provision are preempted under *Mulready*'s reasoning.

58. The Affiliated Pharmacy Prohibition bars PBMs from requiring "patients to use pharmacies that are directly or indirectly owned by the [PBM], including all regular prescriptions, refills or specialty drugs regardless of day supply," 36 O.S. § 6961(C); the Network Provider Restriction Prohibition prohibits PBMs from "restrict[ing] an individual's choice of-in network provider for prescription drugs," *id.* § 6963(D); and the Provider Identification Provision provides that PBMs "shall not in any manner on any material, including but not limited to mail and ID cards, include the name of any pharmacy, hospital or other

providers unless it specifically lists all pharmacies, hospitals and providers participating in the preferred and nonpreferred pharmacy and health networks," *id.* § 6961(D).

59. In rejecting the reasoning that underlies the district court's decision as to the network restrictions challenged in *Mulready*, the Tenth Circuit ruled that "a pharmacy network's scope (which pharmacies are included) and differentiation (under what cost-sharing arrangements those pharmacies participate in the network)[] are key benefit designs for an ERISA plan," and the Act's challenged network restrictions "have an impermissible connection with ERISA plans" because they impose requirements on networks' scope and differentiation and thereby "govern[] a central matter of plan administration." *Mulready*, 78 F.4th at 1198 (third quoting *Rutledge*, 592 U.S. at 87).

60. The network restrictions at issue here similarly prohibit plans from offering particular benefit structures, such as which pharmacies beneficiaries may use and "where beneficiaries can obtain the[ir] drugs," *see id.* The Provider Identification Provision moreover restricts communications to members about those benefit structures, a core plan function. *See, e.g.*, 29 U.S.C. § 1024(b); 29 C.F.R. § 2560.503-1(g). The "logical endpoint" of all these provisions would entail preferred networks effectively "collaps[ing] into a de facto single tier," *see Mulready*, 78 F.4th at 1199, and plans being unable to communicate the details of the benefits and plan structure or design. These provisions have an impermissible connection with ERISA plans and are preempted just like the provisions considered in *Mulready*.

61. Part D also preempts the Affiliated Pharmacy Prohibition and the Network Provider Restriction Prohibition under *Mulready* because "Part D's standards preempt all state laws concerning Part D plans" and "preclude[] States from regulating Part D plans except for licensing and plan solvency," *see id.* at 1206, which neither of these provisions does.

62. But even if Part D preemption were not "akin to field preemption," which it is, *see id.*, and even if it required federal-state overlap, which it does not, "CMS has established guidelines about how Part D plan sponsors must construct their networks," and "Congress and CMS … allow plan sponsors to … promote those sponsors' hand-picked preferred pharmacies over non-preferred pharmacies." *See id.* at 1209.

63. The State has already conceded that Part D preempts the Provider Identification Provision. *Mulready*, 598 F. Supp. 3d at 1209 n.7. That concession is binding on defendants here. But even if the State had not conceded this, Part D preempts the Provider Identification Provision because the provision does not concern licensing or plan solvency, *see Mulready*, 78 F.4th at 1206, and CMS already prohibits plan sponsors from "mislead[ing], confus[ing], or provid[ing] materially inaccurate information to current or potential enrollees." *See* 42 C.F.R. § 423.2262. That regulation overlaps with the Provider Identification Provision and thus would preempt it. *See Mulready*, 78 F.4th at 1209.

E. A Justiciable Controversy Now Exists Between Caremark And Defendants

64. Defendants have previously pursued enforcement actions charging Caremark with violations of the Act, including provisions the Tenth Circuit held preempted in *Mulready*.

65. In the most recent action, the Department charged Caremark with violations of three provisions relevant here—the Affiliated Pharmacy Prohibition, 36 O.S. § 6961(C); the Network Provider Restriction Prohibition, *id.* § 6963(D); and the Discount Prohibition, *id.* § 6963(E)—based on Caremark clients' use of programs requiring plan members to fill prescriptions for maintenance medications through Caremark's mail-order pharmacy or at a CVS retail pharmacy.

66. In an earlier action, the Department charged Caremark with violations of those three provisions as well as the Provider Identification Provision, *id.* § 6961(D), based on Caremark's clients' use of the same programs.

67. The Tenth Circuit's decision in *Mulready*, as discussed, expressly held that ERISA preempts the Discount Prohibition, and the court's reasoning applies equally to the Affiliated Pharmacy Prohibition, the Provider Identification Provision, and the Network Provider Restriction Prohibition.

68. Defendants have made clear that they intend to continue to enforce these provisions against Caremark notwithstanding the Tenth Circuit's decision in *Mulready*.

69. On August 21, 2023, less than a week after the *Mulready* decision was handed down, defendants issued a press release confirming their intent to disregard the obvious implications of the court's ruling on the limits of states' legislative authority in this arena. The Commissioner, for example, declared: "Enforcement of the Act will continue to the maximum ability of *state* law," without regard for the application of *federal* law.

70. On August 28, 2023, less than two weeks after the Tenth Circuit issued its decision in *Mulready*, the Attorney General filed a notice of intervention in the proceedings before an administrative law judge on the charges described above.

71. In that notice of intervention, the Attorney General "assume[d] control of [the] prosecution" and expressed that he "intends to dismiss the present action"—but "without prejudice," and with a plan to "refile the matter when appropriate."

72. On September 12, 2023, the Attorney General filed a notice of dismissal without prejudice in that action. That notice of dismissal emphasizes that the Attorney General dismisses

the claims at issue "without the prejudice to any refiling" and that the "Attorney General intends to refile another enforcement action against Caremark, LLC when it is deemed appropriate."

73. On October 13, 2023, the Attorney General notified Caremark that, as of November 1, 2023, it "will have enforcement authority under the provisions of the [Act]" and requested that Caremark "allow this letter to serve as notice that our office is preparing to issue you an Investigative Demand to ensure Caremark LLC's compliance with the Act."

74. The Attorney General's October 13 letter is signed by Deputy Attorney General Michael Leake and Assistant Attorney General Matthew Willoughby, both of the newly created PBM Compliance and Enforcement Unit.

75. On November 1, 2023, the Attorney General served on Caremark the threatened Investigative Demand, seeking extensive documents and information about Caremark's business in Oklahoma.

76. Defendants have accordingly made clear that they intend to continue to enforce provisions of the Act that the Tenth Circuit did not address—including the Affiliated Pharmacy Prohibition, Provider Identification Provision, and Network Provider Restriction Prohibition—even though the Tenth Circuit's preemption reasoning applies equally to these provisions.

77. The imminent threat of enforcement of these provisions harms Caremark and the plans and members it serves.

78. Threatened enforcement of the Affiliated Pharmacy Prohibition, Provider Identification Provision, and Network Provider Restriction Prohibition require Caremark to either restructure its benefit plans across the country to comply with Oklahoma's demands, even in states that properly refrain from regulating in this exclusively federal sphere; create new,

Oklahoma-specific plan designs for Oklahoma members, even for plans that serve members across state lines; or face possible fines and license revocations for violating Oklahoma law.

79. Oklahoma's threatened enforcement of these provisions also prevents Caremark from employing business practices that drive value for plans and their members. These provisions of the Act interfere with the arms-length market negotiations between PBMs and pharmacies, and not only Caremark but also the plans and members it serves will face higher prescription drug costs as a result.

80. Plans are currently unable to employ benefit designs they have contracted with Caremark to provide. Some of them are now unable to fulfill benefit commitments under collective bargaining agreements. These are benefits structures that plans and their participants want and value. ERISA and Medicare Part D protect the ability to choose them.

CLAIMS FOR RELIEF

Count I: ERISA Preemption

81. Caremark realleges and incorporates by reference each allegation contained in the preceding paragraphs as if set forth fully herein.

82. The Affiliated Pharmacy Prohibition, Provider Identification Provision, and Network Provider Restriction Prohibition "relate to" an employee benefit plan because they have an impermissible "connection with" ERISA plans in that they regulate PBMs serving "third-party payor[s]," *see* 36 O.S. § 6960, which include ERISA-covered health plans, by requiring ERISA plan sponsors to "structure benefit plans in particular ways," including by mandating specific benefits and prohibiting employers from structuring their benefits in certain ways, *see Mulready*, 78 F.4th at 1194 (quoting *Rutledge*, 592 U.S. at 86-87); "interfer[ing] with nationally uniform [ERISA] plan administration," *see id.* (quoting *Gobeille*, 577 U.S. at 320); and causing

an acute economic impact that forces ERISA plans to adopt certain schemes of substantive coverage, *see id.* (citing *Rutledge*, 592 U.S. at 87).

83. Because the Affiliated Pharmacy Prohibition, the Provider Identification Provision, and the Network Provider Restriction Prohibition regulate PBMs' design, structure, and administration of pharmacy benefits on behalf of ERISA health plans, they function as regulations of such plans, which ERISA forbids.

84. Accordingly, ERISA preempts the Affiliated Pharmacy Prohibition, the Provider Identification Provision, and the Network Provider Restriction Prohibition.

Count II: Medicare Part D Preemption

85. Caremark realleges and incorporates by reference each allegation contained in the preceding paragraphs as if set forth fully herein.

86. Medicare Part D's broad preemption precludes states from regulating Part D plans except for regarding licensing and plan solvency. *See Mulready*, 78 F.4th at 1206. Because the Affiliated Pharmacy Prohibition and Network Provider Restriction Prohibition do not concern licensing or plan solvency, Part D preempts those provisions.

87. Part D also preempts the Affiliated Pharmacy Prohibition and Network Provider Restriction Prohibition because those provisions are State laws "with respect to" PBMs and, ultimately, Part D plans, as they establish rules that govern PBM pharmacy networks for Part D plans, *see id.* at 1208 (quoting 42 U.S.C. § 1395w-26(b)(3)), including the promotion of plans' "hand-picked preferred pharmacies," *see id.* at 1209.

88. The Affiliated Pharmacy Prohibition and Network Provider Restriction Prohibition thereby "diminish[] the Federal Government's control over enforcement and detract[] from the integrated scheme of regulation created by Congress." *See id.* at 1205 (quoting *Arizona v. United States*, 567 U.S. 387, 402 (2012)). Indeed, Congress and CMS have established

standards that comprehensively regulate the operations of Medicare Part D plans (and, by extension, PBMs serving those plans, 42 C.F.R. § 423.505(i)), including plan networks, price negotiations and structures, and marketing. *See, e.g.*, 42 U.S.C. § 1395w-104(b)(1)(A)-(B); *id.* § 1395w-102(d)(1)(A); *id.* § 1395w-111(i)(1)-(2); 42 C.F.R. § 423.120(a)(9); *id.* § 423.100; *id.* §§ 423.120(a)(1), (3); *id.* § 423.505(b)(18); *id.* § 423.120(a); *id.* § 423.120(a)(1); *id.* § 423.2262; *id.* § 423.128.

89. These and all other standards governing Part D "supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [prescription drug plans] which are offered by [plan sponsors] under [Part D]." 42 U.S.C. § 1395w-26(b)(3).

90. The State's concession that Part D preempts the Provider Identification Provision, *Mulready*, 598 F. Supp. 3d at 1209 n.7, binds defendants here.

91. Medicare Part D accordingly preempts the challenged provisions.

REQUEST FOR RELIEF

WHEREFORE, Caremark respectfully prays that this Court:

(1) declare that ERISA preempts the Affiliated Pharmacy Prohibition, Provider Identification Provision, and Network Provider Restriction Prohibition;

(2) declare that the Medicare Part D statute preempts the Affiliated Pharmacy Prohibition and Network Provider Restriction Prohibition;

(3) grant preliminary and permanent injunctive relief enjoining defendants and their agents from taking any action under or to enforce the Affiliated Pharmacy Prohibition, Provider Identification Provision, and Network Provider Restriction Prohibition against Caremark; and

(4) grant Caremark such additional or different relief as it deems just and proper.

Respectfully submitted,

CAREMARK, LLC and CAREMARKPCS HEALTH, LLC

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